

## VII. 510(k) SUMMARY OF SAFETY & EFFECTIVENESS

**PROPRIETARY NAME:** Signal™ DBM

**COMMON NAME:** Bone Void Filler Containing Human Demineralized Bone Matrix (DBM)

**REGULATORY CLASS:** Class II

**CLASSIFICATION IDENTIFICATION:** 21 C.F.R. §888.3045 Resorbable calcium salt bone void filler device

**PRODUCT CODE:** MBP, MQV

**PANEL CODE:** 87—Orthopedic Devices

**SPONSOR:** Musculoskeletal Transplant Foundation  
125 May Street  
Edison, NJ 08837  
732-661-0202  
723-661-2189 fax

### INDICATIONS FOR USE:

Signal DBM is a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Signal DBM can be used to fill bone voids in the extremities and pelvis. It is indicated for use in the treatment of surgically-created osseous defects or osseous defects created from traumatic injury.

Signal DBM is for single patient use only.

### DEVICE DESCRIPTION:

Signal DBM is completely resorbable and is composed of donated cortical bone. The bone granules are mixed with sodium hyaluronate (Hy) and carboxymethylcellulose (CMC). Signal DBM is available in sizes of 0.5 cc, 1.0 cc, 2.5 cc, 5.0 cc, and 10.0 cc.

**SAFETY AND EFFECTIVENESS INFORMATION:**

Biocompatibility of Sygnal DBM components has been established through their long history of safe and effective clinical use, further supported by laboratory testing conducted per ISO 10993. Sygnal DBM is single-donor processed using aseptic techniques and is tested for sterility per current USP <71>.

**OSTEOINDUCTIVE POTENTIAL:**

Sygnal DBM is osteoconductive, and has been shown to have osteoinductivity potential in an athymic mouse model. Every lot of final product is assayed *in vivo* for its osteoinductive potential. Standard testing performed in an athymic mouse model must prove positive for lot release. Osteoinduction assay results in the athymic mouse model should not be interpreted to predict clinical performance in human subjects.

**VIRAL CLEARANCE AND INACTIVATION:**

The method for processing the demineralized bone matrix contained in Sygnal DBM was evaluated for its viral inactivation potential. A panel of model potential human viruses representing various virus types, sizes, shapes and genomes were evaluated. The DBM processing methods were determined to provide significant viral inactivation potential for a wide range of potential viruses.



FEB 28 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Musculoskeletal Transplant Foundation  
% Ms. Nancy Bennewitz  
Regulatory Affairs Submission Specialist  
123 May Street  
Suite 300  
Edison, NJ 08837

Re: K073329  
Trade/Device Name: Sygnal™ DBM  
Regulation Number: 21 CFR 888.3045  
Regulation Name: Resorbable calcium salt bone void filler device  
Regulatory Class: Class II  
Product Code: MBP, MQV  
Dated: February 20, 2008  
Received: February 21, 2008

Dear Ms. Bennewitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Nancy Bennewitz

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## V. INDICATIONS FOR USE

510(k) Number (if known): not known

Device Name: Sygnal™ DBM

Indications for Use:

Sygnal DBM is a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Sygnal DBM can be used to fill bone voids in the extremities and pelvis. It is indicated for use in the treatment of surgically-created osseous defects or osseous defects created from traumatic injury.

Sygnal DBM is for single patient use only.

Prescription Use   X   OR Over-The-Counter Use             
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

510(k) Number   K073329